K042970

DEC - 7 2004

510(k) Summary
for
Copan Universal Transport Medium (UTM-RT) System

1. SPONSOR

Copan Diagnostics Inc.
2175 Sampson Avenue, Suite 124
Corona, CA 92879

Contact Person: Norman Sharples
Telephone: 800-216-4016

Date Prepared: October 27, 2004

2. DEVICE NAME

Proprietary Name: Copan Universal Transport Medium (UTM-RT) System
Common/Usual Name: Transport Culture Medium Devices
Classification Name: Transport Culture Medium Devices

3. PREDICATE DEVICES

- Multi-Microbe Collection & Transport System, M4 Medium
  MicroTest Inc.
  K910526
- MicroTest™ Multi-Microbe Collection & Transport System, M4 Medium
  REMEL – Apogent
  [Covered by K910526 due to acquisition of MicroTest Inc. by REMEL-Apogent]

4. DEVICE DESCRIPTION

The Copan UTM-RT System includes a universal transport medium that is room temperature stable and that can sustain viability (and infectivity) of a plurality of organisms that include clinically important viruses, chlamydiae, mycoplasma and ureaplasma during transit to the testing laboratory. The formulation of UTM-RT medium includes protein for stabilization, antibiotics to minimize bacterial and fungal contamination, and a buffer to maintain a neutral pH.

Copan UTM-RT System medium is provided in screw-cap tubes designed for transport of the clinical sample. Copan UTM-RT System is also supplied as a sample collection kit that comprises a package which contains one screw-cap tube of UTM-RT medium and a peel pouch incorporating one or two sterile specimen collection swabs. A range of UTM-RT sample collection kits are available which incorporate different types of shaft swabs which facilitate the collection of specimens from different sites of the patient.

5. INTENDED USE

Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Copan Universal Transport Medium (UTM-RT) System products are substantially equivalent to the predicate transport medium devices. The Copan UTM-RT System product and the predicate devices are similar in design, intended use, and overall function.

The Copan and predicate devices are single-use products intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma. Both the Copan and predicate devices are offered in product configurations with medium supplied alone or in kit formats with medium and specimen collection swab options.

7. PERFORMANCE TESTING

Studies were conducted to evaluate the performance characteristics of the Copan Universal Transport Medium (UTM-RT) System. Recovery studies were performed using the Copan UTM-RT System and a comparative product to determine the ability of the products to maintain viability of various strains of viruses, chlamydiae, mycoplasma and ureaplasma during storage and use. Stability testing was performed on aged Copan UTM-RT products to support the 12-month expiration date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 7 2004

Copan Diagnostics, Inc.
c/o Cynthia A. Sinclair, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: k042970
Trade/Device Name: Copan Universal Transport Medium (UTM-RT) System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I
Product Code: JSM
Dated: October 27, 2004
Received: October 28, 2004

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

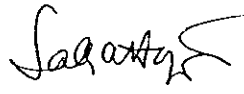
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042970

Device Name: Copan Universal Transport Medium (UTM-RT) System

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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042970